



Government Of Nepal
Ministry of Health
Department of Drug Administration

Issues, Challenges and Way foraward

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Introduction

Organization and management

1. Department Office: Kathmandu
2. Laboratory : National Medicine Laboratory
3. Regional offices:
 - ❖ Nepalgunj
 - ❖ Birgunj
 - ❖ Biratnagar

Introduction

Human Resources: 115

1. Department Office: Kathmandu :**49**

2. Laboratory : National Medicine
Laboratory:**40**

3. Regional offices:**26**

❖ Nepalgunj :9

❖ Birgunj: 8

❖ Biratnagar: 9

लक्षित मुख्य कार्यक्रमहरु

	Target		
Information dissemination on rational use of drug	60		
Publication of Drug bulletin of Nepal (DBN)	3 (15000 Pcs)		
Sample analysis of drug	1000 (~17000)		
<u>GLP audit of Domestic pharmaceutical industry's Laboratory</u>	24 (~50)		

लक्षित मुख्य कार्यक्रमहरु

	Target		
GMP audit of domestic pharmaceutical industry	100 (~125)		
GMP audit of foreign pharmaceutical industry	4 (~250)		
Pharmacy inspection including regional offices	2900 (~14000)		

Current Initiatives

- Regular meeting on good governance
- National essential medicines list finalised
- Online system (DAMS) operationalised
- Risk-based PMS program
- Drug price fixation and implementation
- Aushadhi APP for price transparency
- Performance contract with Health secretary
- Access control into sensitive work areas
- Method validation work on 4 non-pharmacopoeial

Issues And Challenges

- ❑ INFRASTRUCTURE(OP1a1)
- ❑ Human resources(OP1b1)
- ❑ Quality management system(OP2.2)
- ❑ Governance and accountability(OP5.2)
- ❑ Rational use of medicines and containment of AMR(OP7.1)
- ❑ Assessment of service indicators and quality(OP9.2)
- ❑ Legal action and sanction(drug act and rule)

Issues And Challenges..

- Cross-border ingress of medicine and counterfeit medication
- Coordination (intra and inter institutional)
- Regulation beyond medicines(health technology products)
- Dynamic and responsive information system
- Harmonization and good reliance practices

Way Forward

- Upgrade NML infrastructure for testing of biological, cytotoxic, ayurvedic and traditional medicine
- Establish 4 additional provincial offices of DDA
- Develop and outsource annual maintenance plan for preventative maintenance
- Develop replacement plan and procure laboratory instruments

Way Forward..

- Conduct comprehensive needs assessment for
- Training of regulatory staff
- capacity development for regulatory and testing professional staff

Way Forward..

- Update revise NDP, Drug Act/rules
- Update standards and protocols
- Improved testing including PMS
- NML accreditation as per ISO17025 including privately owned testing
- Antimicrobial resistance action plan and enforcement including OTC sales control
- Price and transparency
- Strengthening hospital pharmacy concept
- Facilitating domestic

Way Forward..

- Revise NNF to improve rational prescribing and use of medicine
- Strengthen registration database and information system
- Develop and strengthen web portal including public apps on medicines use, price etc

Result framework(NHSS)

- % of human resources working in DDA trained on regulatory science and testing
- % of technical positions filled
- % GLP and GMP certified domestic industries
- % availability of reference standard for analysis of registered drugs
- % registered pharmacies GPP certified
- % availability of RS for analysis
- % accredited private testing laboratories

Thank You